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U.S. DISTRICT COURT
N.D. OF ALABAMA

IN THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF ALABAMA NORTHEASTERN DIVISION

THE BOARD OF TRUSTEES OF THE UNIVERSITY OF)	
ALABAMA, a public corporation)	
Plaintiff)	
vs.) Civil Action No:	
NEKTAR THERAPEUTICS AL,)	
CORPORATION and NEKTAR)	
THERAPEUTICS, INC.)	
)	
Defendants.)	

COMPLAINT

Plaintiff, The Board of Trustees of The University of Alabama, a public corporation, on behalf of one of its divisions, the University of Alabama in Huntsville (hereinafter "UAH" or "Plaintiff") states the following for its complaint against Nektar Therapeutics AL, Corporation and Nektar Therapeutics, Inc. (hereinafter referred to collectively as "Nektar" or "Defendants"):

PARTIES

1. Plaintiff, The Board of Trustees of the University of Alabama, is a public corporation and instrumentality of the State of Alabama organized and existing under the Constitution and laws of the State of Alabama.

- 2. Defendant Nektar Therapeutics AL, Corporation is an Alabama corporation with its principal place of business in Huntsville, AL.
- 3. Defendant Nektar Therapeutics, Inc. is a Delaware corporation, with its principal place of business in San Carlos, CA and with a regular and established place of business in Huntsville, AL.

JURISDICTION AND VENUE

- 4. This action arises under the Patent Laws of the United States, 35 U.S.C. § 1 et seq., as hereinafter more fully appears. This Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331 and 1338(a). This Court has jurisdiction over Plaintiff's related state and common-law claims pursuant to 28 U.S.C. §§ 1338 and 1367.
- 5. Defendants have committed acts of infringement and have a regular and established place of business in the judicial district in which this court sits.
- 6. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391 and 1400.

FACTUAL BACKGROUND

7. Dr. J. Milton Harris and Dr. M. R. Sedaghat-Herati, former faculty members at UAH, invented and discovered a new technology involving polyethylene glycol (PEG) compounds and processes.

- 8. On November 28, 1990, an application for a patent entitled Preparation and Use of Polyethylene Glycol Propionaldehyde was filed with the United States Patent and Trademark Office. A copy of the Patent Application is attached as Exhibit A and incorporated by reference.
- 9. All of the inventors' rights, title and interest in the patent were assigned to The University of Alabama in Huntsville, a division of The Board of Trustees of The University of Alabama. This assignment was recorded in the United States Patent and Trademark Office on February 26, 1993.
- 10. Prior to the issuance of any patent, Shearwater Polymers, Inc. (hereinafter "Shearwater") began negotiating with UAH to obtain a license to use the new technology described in the Patent Application.
- 11. Shearwater represented to UAH that it had the capability to utilize and exploit the commercial applications of this new technology.
- 12. Shearwater represented that if UAH would grant it a license to use this new technology, it would pay UAH a reasonable royalty for the sale of any product described, in whole or in part, by the Patent Application or any product created using any of the processes, in whole or in part, described in the Patent Application.

- 13. On June 17, 1993, UAH entered into an exclusive license agreement with Shearwater. A copy of the License Agreement is attached as Exhibit B and incorporated by reference.
- 14. The License Agreement requires Shearwater to pay UAH a royalty of 7% of the gross revenue from the sales of all products described, in whole or in part, in the Patent Application or manufactured through processes described, in whole or in part, in the Patent Application.
- 15. On October 12, 1993, United States Patent No. 5,252,714 was duly and legally issued for the invention and identified UAH as the assignee. Since that time UAH has been, and still is, the sole owner. A copy of Patent No. 5,252,714 is attached, as Exhibit C and incorporated by reference.
- 16. The patented technology was extremely valuable because it enhances delivery performance of most major drug classes.
- 17. Because it held an exclusive license to use UAH's patented and licensed technology, Shearwater's value increased dramatically and, in 2001, it was purchased by Inhale Therapeutic Systems, Inc. for approximately \$191 million.
- 18. Inhale Therapeutic Systems, Inc. changed its name to Nektar Therapeutics, Inc. in 2003.

- 19. Shearwater Polymers, Inc. has changed its name to Nektar Therapeutics AL, Corporation and remains a wholly owned subsidiary of Nektar Therapeutics, Inc.
- 20. Since June 17, 1993, Defendants have commercially exploited UAH's patented and licensed technology.
- 21. In 1995, using the technology it licensed from UAH, Shearwater entered into a Supply and License Agreement with Amgen, Inc. to provide Amgen with Polyethylene Glycol Propionaldehyde to improve the performance of Amgen's pharmaceuticals.
- 22. Recognizing UAH's ownership of the patented technology and its rights under the Licensing Agreement with Shearwater, Amgen required that UAH consent to Amgen's agreement with Shearwater and Amgen's use of UAH's patented and licensed technology.
- 23. One of Amgen's pharmaceuticals using UAH's patented and licensed technology is Neulasta, a drug prescribed to enhance the immune system of cancer patients being treated by chemotherapy.
- 24. Over the past ten years, Defendants have voluntarily paid UAH \$1,664,127.66 in royalties for sales of Neulasta.

- 25. With the market for Neulasta greatly expanding, UAH's royalties had been dramatically increasing in recent years. In fact, the annual sales of Neulasta are expected to top \$2 billion within the next five years.
- 26. On May 10, 2005, Defendants informed UAH that they would pay no more royalties for use of its licensed and patented technology with regard to Neulasta.
- 27. Although Defendants' licensing agreement with Amgen specifically recognizes the use of UAH's patented and licensed technology and Defendants have voluntarily paid UAH for past sales of Neulasta, Defendants now assert that Neulasta is made with a different polyethylene glycol compound and have refused to make any future royalty payments.

COUNT I (PATENT INFRINGEMENT)

- 28. Plaintiff adopts and incorporates herein all allegations of paragraphs 1-27 as if fully set forth herein.
- 29. On October 12, 1993, United States Patent No. 5,252,714 was duly and legally issued to UAH for the invention, and since that time UAH has been, and still is, the sole owner.
- 30. By their actions described above, Defendants have infringed and are infringing on UAH's patent. Such infringement is deliberate, willful,

- intentional, and with full knowledge of the existence, scope, and validity of Plaintiff's patent.
- 31. As a result of Defendants' infringement, Plaintiff has suffered damages in an amount to be determined at trial.

COUNT II (DECLARATORY JUDGMENT)

- 32. Plaintiff adopts and incorporates herein all allegations of paragraphs 1-30 as if fully set forth herein.
- 33. Defendants intend to continue manufacture, distribution, and sale of UAH's licensed and patented technology, thus depriving Plaintiff of considerable future income that cannot accurately be calculated.
- 34. For this reason, Plaintiff has no adequate remedy at law and requests that:
 - (a) UAH be adjudged the record owner of all rights, title, and interest in and to United States Patent No. 5,252,714;
 - (b) United States Patent No. 5,252,714 be adjudged to be good and valid in law and to have been infringed by Defendants;
 - (c) Defendants, their officers, directors, servants, agents, employees, and attorneys be permanently enjoined from further infringement against United States Patent No. 5,252,714;

- (d) Defendants, their officers, directors, servants, agents, employees, and attorneys be permanently enjoined from further infringing United States Patent No. 5,252,714;
- (e) Defendants, their officers, directors, servants, agents, employees, and attorneys be permanently enjoined from advertising, offering for sale, or selling any PEG compounds or any PEGylation technology which by imitation or other similarity to those of Plaintiff are likely to cause confusion, mistake or cause persons to be deceived into the belief that Defendants' products are Plaintiff's products or that Defendants and their products are authorized by Plaintiff or are endorsed by Plaintiff or are sponsored by Plaintiff or are connected in some way with Plaintiff;
- (f) All products, circulars, brochures, advertisements, and other documentation in the possession, custody, or control of Defendants, and all PEG compounds that, if used, violate the injunction herein granted, be delivered up to Plaintiff as the Court shall direct;
- (g) Defendants be required to account to Plaintiff for any and all profits derived by them, and all damages sustained by Plaintiff, resulting from the acts complained of herein; and

(h) Plaintiff be awarded such other and further relief as the Court deems proper.

COUNT III (BREACH OF LICENSE AGREEMENT)

- 35. Plaintiff adopts and incorporates herein all allegations of paragraphs 1-33 as if fully set forth herein.
- 36. UAH has an exclusive License Agreement with Defendants.
- 37. Pursuant to this License Agreement, Defendants are required to pay UAH a royalty of 7% of the gross revenues for the sale of Licensed Products. The obligation of Defendants to make royalty payments to UAH under said License Agreement is not dependent upon the existence of a valid patent.
- 38. Defendants have failed to pay UAH the royalties due pursuant to this License Agreement.
- 39. As a result of Defendants' breach of the Licensing Agreement, Plaintiff has suffered damages in an amount to be determined at trial.

COUNT IV – (VIOLATION OF ALABAMA TRADE SECRETS ACT)

- 40. Plaintiff adopts and incorporates herein all allegations of paragraphs 1-39 as if fully set forth herein.
- 41. Defendants obtained UAH's trade secrets relating to the preparation and use of Polyethylene Glycol Propionaldehyde through improper means.
- 42. Defendants have used and disclosed UAH's trade secrets.

- 43. Defendants' misappropriation of UAH's trade secrets violated Alabama's Trade Secrets Act (ALA. CODE 8-27-1 et seq.).
- 44. As a result of Defendants' acts, Plaintiff has been damaged in an amount to be determined at trial.

COUNT V – (UNJUST ENRICHMENT)

- 45. Plaintiff adopts and incorporates herein all allegations of paragraphs 1-44 as if fully set forth herein.
- 46. Defendants have reaped hundreds of millions of dollars in profit from the use of UAH's licensed and patented technology, but have refused to adequately compensate UAH for this technology.
- 47. Defendants have been and continue to be unjustly enriched by these profits which inured to the benefit of and conferred substantial value on Defendants, to the detriment of Plaintiff.
- 48. As a result of Defendants' acts, Plaintiff has been damaged in an amount to be determined at trial.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays that the following judgment be entered against Defendants:

(a) Plaintiff be adjudged the record owner of all rights, title, and interest in and to United States Patent No. 5,252,714;

- (b) United States Patent No. 5,252,714 be adjudged to be good and valid in law and to have been infringed by Defendants;
- (c) Defendants, their officers, directors, servants, agents, employees, and attorneys be permanently enjoined from further infringement against United States Patent No. 5,252,714;
- (d) Defendants, their officers, directors, servants, agents, employees, and attorneys be permanently enjoined from further infringing United States Patent No. 5,252,714;
- (e) Defendants, their officers, directors, servants, agents, employees, and attorneys be permanently enjoined from advertising, offering for sale, or selling any PEG compounds or any PEGylation technology which by imitation or other similarity to those of Plaintiff are likely to cause confusion, mistake or cause persons to be deceived into the belief that Defendants' products are Plaintiff's products or that Defendants and their products are authorized by Plaintiff or are endorsed by Plaintiff or are sponsored by Plaintiff or are connected in some way with Plaintiff;
- (f) All products, circulars, brochures, advertisements, and other documentation in the possession, custody, or control of Defendants,

- and all PEG compounds that, if used, violate the injunction herein granted, be delivered up to Plaintiff as the Court shall direct;
- (g) Defendants be required to account to Plaintiff for any and all profits derived by them, and all damages sustained by Plaintiff, resulting from the acts complained of herein; and
- (h) An award of compensatory damages, in an amount to be decided by a jury, for Defendants' infringement of Patent No. 5,252,714.
- (i) Plaintiff be awarded treble damages, in an amount to be decided by a jury, on account of the willful and intentional character of Defendant's infringing acts, as provided by 35 U.S.C. § 284;
- (j) Plaintiff be awarded all attorney fees incurred in the prosecution of this lawsuit;
- (k) Plaintiff be awarded all interest and costs; and
- (l) Plaintiff be awarded such other and further relief as the court deems proper.

JURY DEMAND

Plaintiff demands a trial by jury on all claims and issues so triable.

Respectfully submitted on this the 13th day of July, 2005.

W. Stancil Starnes (ASB-1922-E57W)

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